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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,242	04/13/2004	Daniella I. Zheleva	CCI-014CP2	9212
959	7590	11/02/2006		EXAMINER
LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			CHISM, BILLY D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/771,242	ZHELEVA ET AL.	
	<b>Examiner</b> B. Dell Chism	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 August 2006.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 49-73 is/are pending in the application.
- 4a) Of the above claim(s) 57-59, 63, 64, 67 and 68 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 49-56, 60-62, 65-66, 69-73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

DETAILED ACTION

**Withdrawal of Objections and Rejections**

1. The rejections and/or objections made in the prior office action mailed on 07 February 2006, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 07 August 2006 will be addressed to the extent that they pertain to the present grounds of rejection.

2. Claims 49-73 are pending. Claims 49-56, 60-62, 65-66, 69-73 are rejected, with claims 57-59, 63, 64, 67 and 68 withdrawn from consideration.

3. Applicants traverse the withdrawal of claims 57-59, 63-64 and 67-68 in the previous office action. The examiner maintains the withdrawal insofar as the claims are drawn to subject matter that has not been found allowable. The elected species of the previous office action was indicated as allowable, however, the entire claim set is still open to many species that have not been deemed allowable. If Applicants wish to have those claims that read on the elected species allowed, then Applicants must limit those claims to that elected species. Since the claims remain open to other species, the examiner moved on to another species that was not found allowable. Therefore, the prosecution was limited only to those claims that presently read on that additional single species. The withdrawn claims are to other species that have not been searched; therefore, the claims are withdrawn from consideration. Since the claims are not being currently prosecuted because those claims do not read on the instantly prosecuted species, and since they read on other species that have not been prosecuted, they must be withdrawn under species practice. As far as the elected species being free of the art, if any of those withdrawn claims read

upon the allowable species and Applicants wish to have those claims indicated as allowable, then Applicants must limit those claims the allowable species only. Consequently, those claims have not been limited in such a manner; therefore, those claims remain withdrawn from consideration.

***Claim Objections***

4. Objections to claims 50 and 71-73 are withdrawn.

***Claim Rejections - 35 USC § 112***

5. (Withdrawn) Rejections of Claims 50-56, 60-62, 65066 and 69-70 under 35 U.S.C. 112, second paragraph, as being indefinite are withdrawn as rendered moot via amendments to the claims.

***Claim Rejections - 35 USC § 102***

6. (Maintained) Rejection of Claims 49-56, 60-62, 65-66, 69-71 under 35 U.S.C. 102(b) as being anticipated by WO 97/42222 ('2222) is maintained. '2222 teaches the species RRLIF (page 63, lines 16-19). This species meets and anticipates the limitations of the instant claims 49-56, 60-62, 65-66, 69-71, additionally, '2222 teaches many variants, i.e. page 75 line 20, of the instantly claimed formulas as applied by the variant definitions in the instant specification.

Applicants argue that the '2222 reference does not anticipate the rejected claims because the reference does not teach a pentamer meeting the limitations of formula V (SEQ ID NO: 293). The examiner points to the fact that the instant claim set is to a product (a peptide consisting of the formula V...) wherein the product is limited to a pentamer with defined limitations as is set out in instant claim 49, for example. The '2222 reference teaches a pentamer that is defined by the limitations of the instant claim 49, and that is further specifically claims in claim 71.

Applicants argue that the sequence was neither isolated nor synthesized in the reference, and

therefore, the reference fails to teach the sequence. The examiner does not find this persuasive, especially in light of the specification of the reference at page 5 lines 17-24. Clearly, one of skill in the art would see this pentamer as being taught. The specification at page 5 would lead one of ordinary skill in the art to believe that the pentamer was taught especially since page 63 clearly defines the pentamer of RRLIF “where the bold characters are essential for activity and the underlined residue contributes significantly to inhibitory activity.” Furthermore, the specification at page 5 requires a peptide sequence “consisting of the motif”, wherein this language is closed and represents the motif pentamer of RRLIF at page 63. The specification is clear that the pentamer consists of the “critical residues” and then discloses the residues. Therefore, the ‘2222 reference clearly defines a peptide sequence consisting of the pentamer. One of skill in the art would read the ‘2222 specification as meeting the limitations of the instant claims.

7. (Maintained) Rejection of Claims 49-56, 60-62, 65-66, 69-71 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,962,792 B1 ('792) is maintained. The '792 patent teaches RRLIF (SEQ ID NO: 12), which meets the limitations of the instant claims 49-56, 60-62, 65-66, 69-71. Additionally, the '792 patent teaches variants of the RRLIF penta-peptide as they are described in the instant specification, wherein the variants of peptide formula V are “modified by at least one of a deletion, addition or substitution of one or more amino acid residues”, at page 32, lines 25-31.

Applicants argued the '792 reference and the '2222 reference together and for substantially the same reasons. Therefore, the arguments above also apply in the maintaining of this rejection. The '792 reference clearly teaches SEQ ID NO: 12 which is the RRLIF sequence

as instantly claimed. Whether or not the sequence of '792 is a motif does not give weight to the Applicants' argument. The sequence is taught and disclosed separately as evidenced by the individual sequence listing of SEQ ID NO: 12 and as taught in the '792 specification. The sequence listing is not subject to "comprising" or "consisting of" language; however, the sequence listing is a listing of those sequences that are part of the patent. Therefore, when performing a sequence search, the RRLIF sequence was found, the sequence meets the instantly claimed limitations and is anticipated by the reference.

***Claim Rejections - 35 USC § 103***

8. (Maintained) Rejections of Claims 49-56, 60-62, 65-66, 71-73 under 35 U.S.C. 103(a) as being obvious over '2222, (cited above) are maintained. At page 5, lines 17-21 and at pages 79-80, '2222 teaches the formula xyLzF, wherein x is Arginine and y and z are any amino acid. This formula and the limitations on the open residues renders obvious many variants and sequences of the instantly claimed formula V sequence of claims 49-56, 60-62, 65-66, 71-73, i.e. SEQ ID NOS: 294, 297, 300, 321, 324, 327, 348, 351, 354 and 377 of claims 71-73. This is asserted further by the '2222 specification at page 63 wherein the '2222 teaches the "critical residues" found in the larger sequence. It would be obvious to one of ordinary skill in the art to use the pentamer disclosed at page 63 of '2222 in light of the specification at page 5 of '2222. The motivation to do so and the reasonable expectancy of success flow from the entire disclosure of '2222 wherein the specification repeatedly teaches that it is the 5 amino acid residues of amino acids 155-160 of the full length p21WAF1 that are critical to the activity and that it is the five amino acids that contain the Cdk4 inhibition (see page 5 of '2222). This goes to Applicants arguments that their sequences are specifically to p21 fragments capable of preferentially binding

Art Unit: 1654

with CDK2 and that this was not known at the time of the '2222 filing. This argument is rendered moot by the fact that the instant claims are drawn only to a peptide consisting of the formula V (SEQ ID NO: 293) and not to the methods of using or making. Therefore, to render the claims obvious, the peptide need only be disclosed in the prior art in such a way as to provide the skilled artisan with the motivation to possess the invention for whatever purpose the art requires. Despite the lack of knowledge that the presently claimed peptides preferentially bind with CDK2, the prior art would motivate one of ordinary skill to use them for inhibiting Cdk4 as suggested in '2222. In so doing, one would be motivated to make and use the peptides as discussed in the '2222 reference and therefore, the peptides would be obvious.

#### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. (Maintained) Claims 49-56, 60-62, 65-66 and 70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-22, 24-

25, 58-64, 66, 70-78 and 80-83 of copending Application No. 09/726,470 ('470). The '470 claims are drawn to many peptide sequences that comprise the instantly claimed peptide formula V of instant claims 49-56, 60-62, 65-66, and 70, i.e. the '470 claimed sequences comprise the sequence --RX<sub>4</sub>LX<sub>5</sub>F--. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to various sequence possibilities and variants of peptide formula V. Due to the indefiniteness of the instant claims regarding whether the claim language is opened or closed, the instant claims are interpreted as being open language for purposes of this rejection. Therefore, the '470 claims render obvious the instant claims wherein all the required limitations are claimed. In the case that the language is to be closed by amendment, it should be noted that the claims would still render obvious variants of the instantly claimed peptide formula V.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1654

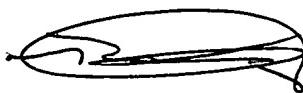
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. No claims are allowed. The elected species SEQ ID NO: 295 is still indicated as allowable. Claims 49-56, 60-62, 65-66, 69-73 are rejected, with claims 57-59, 63, 64, 67 and 68 withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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